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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/414,643	10/08/1999	JOHN E. PILETZ	147/37315CP	3638

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EXAMINER	
LAZAR WESLEY, ELIANE M	
ART UNIT	PAPER NUMBER

1646

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/414,643

Applicant(s)

Piletz

Examiner

Eliane Lazar-Wesley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 25, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16-24 and 27-40 is/are pending in the application.
- 4a) Of the above, claim(s) 27-36, 39, and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-24, 37, and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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## DETAILED ACTION

### *Priority*

1. Applicants recite , in the first paragraph of the specification, that the instant application is a division of US application 08/922,635, filed September 03, 1997, which is a CIP of US application 08/650,766, filed May 20, 1996, which is related to provisional application 60/12,600, filed March 01, 1996, abandoned.

The US applications have issued as patents, and the status of the applications should be updated.

Furthermore, the oath does not refer to application 08/922, 635, and correction is required.

2. Applicant's election with traverse of Group I, claims 16-24 and 37-38, in Paper No. 10 filed October 25, 2001 is acknowledged. The traversal is on the ground(s) that the claims of Group II are to a process that requires culturing a host cell to express the amino acid sequence of Group I. This is not found persuasive for the reasons of record, because the practice of the method of Group II requires a nucleic acid, which is a product different from the polypeptides of Group I.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-24 and 37-38 are under consideration.

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***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 16-21, 23, 24, 37, 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 16-21, 23, 24, 37, 38 recite a polypeptide having at least 90% identity with the polypeptide of SEQ ID No:5 or 6. However, while the originally filed claims recite a polypeptide having at least 80% identity to SEQ ID No:5 or 6, the Examiner could not find support in the specification as filed of polypeptides having at least 90% identity to SEQ ID No:5 or 6, and this constitutes new matter.

Claims 17 and 18 are to a polypeptide of about 35-45kDa, or 37kDa. This polypeptide contains an amino acid sequence at least 90% identical to SEQ ID No:6. However, the specification, at page 8, line 24 through page 9, line 3, discloses that the polypeptide of SEQ ID No:6, which has 390 amino acids, has a molecular weight of about 35 to 50kDa, , more particularly 43kDa.

Claim 20 is to a polypeptide having a molecular weight of 60 to 85 kDa . This polypeptide contains an amino acid sequence at least 90% identical to SEQ ID No:5, which has 651 amino acids.

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However, the specification, at page 8, line 21-22, discloses that the polypeptide of SEQ ID No:5, has a molecular weight of about 50 to 80 kDa.

The specification does not support the claims, and it does not appear that Applicants were in possession of the invention as claimed.

Claim 21 is objected to as depending on rejected claim 20. However, the specification supports, at page 8, line 22-23, a polypeptide of 70 kDa.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 16-18, 22-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-33 of copending Application No. 09/389,487. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because it appears that the instant SEQ ID No:6 (390 amino acids) is identical to SEQ ID No:7 filed in 09/389,487.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

December 14, 2001

*ELW*

  
**LORRAINE SPECTOR  
PRIMARY EXAMINER**